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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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PAUL T. CLARK
FISH & RICHARDSON
28 STATE ST.
BOSTON, MA 02109

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GROUP 120

EXAMINER	
SIESSER, J	
ART UNIT	PAPER NUMBER
127	12

DATE MAILED: [redacted]

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

[X] This application has been examined [X] Responsive to communication filed on Dec 13, 1985 [ ] This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~_____~~ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. [X] Notice of References Cited by Examiner, PTO-892.
2. [ ] Notice re Patent Drawing, PTO-948.
3. [ ] Notice of Art Cited by Applicant, PTO-1449
4. [ ] Notice of informal Patent Application, Form PTO-152
5. [ ] Information on How to Effect Drawing Changes, PTO-1474
6. [ ] _____

Part II SUMMARY OF ACTION

1. [X] Claims 1, 3, 5, 7, 9-15, 17-31, 33-35, 37, 38 and 40-43 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. [ ] Claims 2, 4, 6, 8, 16, 32, 36, 39 have been cancelled.

3. [ ] Claims _____ are allowed.

4. [X] Claims 1, 3, 5, 7, 9-15, 17-31, 33-35, 37, 38 and 40-43 are rejected.

5. [ ] Claims _____ are objected to.

6. [ ] Claims _____ are subject to restriction or election requirement.

7. [X] This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.

8. [ ] Allowable subject matter having been indicated, formal drawings are required in response to this Office action.

9. [ ] The corrected or substitute drawings have been received on _____. These drawings are [ ] acceptable; [ ] not acceptable (see explanation).

10. [ ] The [ ] proposed drawing correction and/or the [ ] proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been [ ] approved by the examiner. [ ] disapproved by the examiner (see explanation).

11. [ ] The proposed drawing correction, filed _____, has been [ ] approved. [ ] disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.

12. [ ] Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [ ] been received [ ] not been received

    [ ] been filed in parent application, serial no. _____; filed on _____.

13. [ ] Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. [ ] Other

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failure to provide an enabling disclosure . The deposit rejection of the previous Office action is repeated. The declaration submitted on Dec. 13, 1985 has been considered. However, the declartion is insuffient because (1) there is no assurance that the deposit will be permanent, i.e. at least 30 years or for 5 years after the date of the last request, whichever is longer and (2) replacement is promised only for the lifetime of the patent.

Claims 1, 3, 5, 7, 9-15, 17-31, 33-35, 37, 38 and 40-43 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the above objection to the specification.

Claims 1, 3, 5, 7, 9-15, 17-31, 33-35, 37, 38 and 40-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as

being unpatentable over claims 1-26, 29-32 and 35-37 of copending application serial no. 548,211. A'though the conflicting claims are not identical, they are not patentably distinct from each other because application '211, which is still pending claims hormones in general, and teaches LH is particular.

Claims 1, 5, 7, 10, 12-15, 17, 19, 20, 33, 34, 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to mammalian cells. See MPEP 706.03(n) and 706.03(z).

Applicants claim all cells as hosts, but show expression only in mammalian cell lines. Further support for this position is found in the Kolata Science article (v 223, p805) which states that microbial hosts are unable to process the proteins into glycoproteins.

Claims 33, 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 is incomplete in failing to recite all the critical steps of the process. Is stands, only the beta subunit is being made. Also, claim 33 has a typographical error in "procuding" . Claim 34 has no antecedent basis for "the alpha subunit".

Claim 3 is rejected under 35 U.S.C. 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 3 claims LH, the subject of claim 1.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Pierce et al.

Claims 1 and 3 are rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Fiddes et al 1980.

Fiddes et al describe the nucleic acid sequence of LH. If thus appears that the LH was isolated in order for this determination to be made. Thus applicants claimed LH appears to be the same as, or inherently present as that described in Fiddes et al.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 5, 7, 9, 10, 11, 12, 18, 21-23, 33-35, 37, 38 and 40-43 are rejected under 35 U.S.C. 103 as being unpatentable over Fiddes et al (1981), Fiddes et al (1980) and Pierce et al.

Fiddes et al (1981) teach the cloning of the alpha subunit of the glycoprotein hormones. Fiddes et al (1980) teach the cloning of the beta subunit of HCG and that the beta sequence of LH is also known in the art. Pierce et al teach that the alpha and beta subunits are known to associate in vitro (page 487) and that in a nature, the two subunits are made independently, then

join together to form a complete hormone. Thus in the absence of unexpected results, it would be obvious to one of ordinary skill in the art to clone both the alpha and beta chains in a single cell (either on the same vector or on separate vectors) to produce two chains which assemble into a functional hormone, as all the elements of this system function in their known and expected manner.

Claims 13-15, 16, 19, 20 and 24-31 are rejected under 35 U.S.C. 103 as being unpatentable over Fiddes et al (1981), Fiddes et al (1980) and Pierce et al as applied to claims 5, 7, 9, 10, 11, 12, 18, 21-23, 33-35, 37, 38 and 40-43 above, and further in view of Moriarty et al, Reddy et al, Hamer et al and Sarvier et al. The methods and vectors, in general, are obvious as discussed supra. Particular vectors and promoter sequences used by applicant to control the production of the foreign polypeptides are also known in the art: SV late promoter (Moriarty et al), SV early promoter (Reddy et al), and mouse metallothionein promoter (Hamer et al). Vectors such as bovine papilloma virus are also commonly used to transform eukaryotic cells (Sarver). Thus it would be obvious to one of ordinary skill in the art to clone one chain of the protein by placing it under the control of a first known promoter and to clone the second chain of the protein by placing it under control

of a second promoter. In combining the know elements, lack continue to function in its known manner to produce a known and expected result, and their placement on the vector(s) is but an arbitrary choice of experimental design. In further support of this conclusion, applicants attention is drawn to the Feb. 24 Science article describing applicants invention where the assignee characterized the methods as well-known.

The declaration of Dr. Skoultchi has been considered, but is not deemed persuasive in light of the Pierce et al teaching that the subunits assemble in vitro.

Any inquiry concerning this communication should be directed to Joanne M. Giesser at telephone number 703-557-3920.

Giesser:bjk

A/C 703

557-3920

3/5/86

THOMAS G. WISEMAN
SUPERVISORY PATENT EXAMINER
ART UNIT 127